

Statement of Deficiencies	(X1) Provider/Supplier/CLIA Identification Number 21D2264828	(X3) Date Survey Completed 11/18/2024
Name of Provider or Supplier John G Deleonibus Dpm Pa	Street Address, City, State 2086 Generals Hwy #101, Annapolis, MD	
For information on the provider's plan to correct this deficiency, please contact the provider or the state survey agency.		

(X4) ID Prefix Tag	Summary Statement of Deficiencies
D5217	<p>EVALUATION OF PROFICIENCY TESTING PERFORMANCE CFR(s): 493.1236(c)(1)</p> <p>At least twice annually, the laboratory must verify the accuracy of any test or procedure it performs that is not included in subpart I of this part.</p> <p>This STANDARD is not met as evidenced by: Note: This is a repeat deficiency. The laboratory was cited during the initial survey completed on 08/02/2023 for not ensuring that all gene targets on the molecular wound and fungal panel assays were verified for accuracy at least twice annually. The laboratory's plan of correction stated that this would be implemented by 09/23/2023. Based on review of the test menu, review of the proficiency testing (PT) provider's catalog, and interview with the general supervisor (GS), the laboratory failed to ensure that all gene targets for the molecular wound and fungal panel testing were verified for accuracy at least twice annually in 2024. Findings: 1. The laboratory performed two molecular assays: 1) a wound panel that tested for 26 pathogen and 9 antibiotic resistance gene targets and 2) a fungal panel that tested for 20 pathogen and 1 antibiotic resistance gene targets. 2. The laboratory enrolled with American Proficiency Institute (API) in PT modules for molecular blood and nail panels. All targets included in each API module were listed in the 2024 Catalog of Programs (catalog). 3. The following gene targets from the wound panel were not included in the API catalog: Citrobacter freundii/braakii, C. koseri, Prevotella bivia, and Staphylococcus saprophyticus. 4. The following gene target from the fungal panel was included in the API catalog, but was not reported by the laboratory on any of the three 2024 PT events: Scytalidium dimidiatum. 5. The following antibiotic resistance gene targets were not included in the API catalog: dfrA, qnr, and sul. 6. During the survey on 11/18/2024 at 2:00 PM, the TP confirmed that not all gene targets from the laboratory's wound and fungal panel were included in API's PT modules and the laboratory performed no split sample testing in 2024.</p>

D5433

MAINTENANCE AND FUNCTION CHECKS

CFR(s): 493.1254(b)(1)

For equipment, instruments, or test systems developed in-house, commercially available and modified by the laboratory, or maintenance and function check protocols are not provided by the manufacturer, the laboratory must establish a maintenance protocol that ensures equipment, instrument, and test system performance that is necessary for accurate and reliable test results and test result reporting. The laboratory must perform and document the maintenance activities specified in paragraph (b)(1)(i) of this section.

This STANDARD is not met as evidenced by:

Based on review of the laboratory records, standard operation manual (SOP) and interview with the general supervisor (GS), the laboratory did not have written policies and procedures for maintenance of the centrifuge and pipettes used in the laboratory. Findings: 1. The laboratory has centrifuge used for the preparation of treated specimens. The laboratory records show that calibration was performed on the centrifuge in November 2024. The SOP has no written policies and procedures for the frequency of calibration of the centrifuge used in the laboratory. 2. The laboratory's SOP requires annual calibration of the pipettes used in the laboratory. The laboratory records for 2023 and 2024 show that the pipettes have not been calibrated as required. 3. During the survey on 11/18/24 at 2:00 PM, the GS confirmed that the SOP has no written policies and procedures for calibration of the centrifuge used in the laboratory and that the pipettes had not been calibrated annually per the SOP's procedures.

D6094

LABORATORY DIRECTOR RESPONSIBILITIES

CFR(s): 493.1445(e)(5)

The laboratory director must ensure that the quality assessment programs are established and maintained to assure the quality of laboratory services provided and to identify failures in quality as they occur.

This STANDARD is not met as evidenced by:

I. Based on review of the laboratory procedures, competency records, and interview with the general supervisor (GS), the laboratory director (LD) failed to ensure that all annual competency was completed each year. Findings: 1. The laboratory procedures require an annual evaluation of laboratory staff. The competency evaluation records for 2023 and 2024 show that the initial evaluation of technical supervisor was performed on 09/07/2023. There were no evaluations for 2024. 2. During the survey on 11/18/2024 at 2:00 PM, the GS confirmed that there were no evaluations available for the TS for the year of 2024. II. Based on review of the job description of the technical supervisor (TS), and interview with the general supervisor (GS), the laboratory director (LD) failed to define what is to be scanned to the TS on a monthly basis, when the monthly documents are to be scanned, and the turnaround time for the evaluation of the documents to ensure that problems are identified and appropriate follow-up is implemented in a timely manner. Findings: During the survey on 11/18 /2024 at 2:00 PM, the GS confirmed that the job description of the TS failed to define what is to be scanned to the TS on a monthly basis, when the monthly documents are to be scanned, and the turnaround time for the evaluation of the documents to ensure that problems are identified and appropriate follow-up is implemented in a timely manner. III. Based on review of the "Submitting Monthly QA [quality assessment]

Documents" procedure, and interview with the general supervisor (GS), the laboratory director (LD) failed to approve all QA policies and procedures. Findings: During the survey on 11/18/2024 at 2:00 PM, the GS confirmed that the "Submitting Monthly QA Documents" procedure had not been approved by the LD.